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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,491	10/01/2003	Jean-Pascal Hirt	235016US26	4669
22850	7590	09/28/2006	EXAMINER	
C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			ROY, ANURADHA	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,491

Applicant(s)

HIRT ET AL.

Examiner

Anuradha Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,14-16,21,23-29,46-48,53,55-70 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-13,17-20,22,30-45,49-52,54,71 and 73-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date see Other.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: 7/31/06, 10/24/03, 10/01/03.

DETAILED ACTION

Restrictions

Claims 2, 3, 14-16, 21, 23-29, 46-48, 53, 55-70, & 72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 7, 2006.

Information Disclosure Statement

The information disclosure statement filed on October 10, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a few of the foreign patents fail to have a English translation. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13, 17-20, 22, 30, 45, 49-52, & 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (US Patent No. 6,343,717).

In regards to claims 1 & 30, Zhang et al. discloses an evaluation or diagnostic kit comprising a plurality of applicators containing different test substances capable of containing at least one compound at different concentrations, each applicator comprising:

a tube (40);

a plug inside the tube (58); and

at least one test substance (48) contained in an inside space of the tube defined at a first end by the plug, the plug being arranged, in use, to be expelled together with the test substance when said test substance leaves the inside space of the tube (Figure 3).

Regarding claim 13 & 45, Zhang et al. discloses a tube, wherein the inside space is defined at a second end (46), remote from the first, by a breakable portion (42).

With regard to claim 17 & 49, Zhang et al. discloses a kit, wherein the applicator includes a retaining element for retaining the breakable portion on the applicator after it has been broken off (Figure 3, 42).

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In regards to claim 18 & 50, Zhang et al. discloses a kit, wherein the tube (40) is provided at one end with an applicator element (72), the applicator element being separated from the test substance prior to use, by the plug (Figure 2, 58).

With respect to claim 19 & 51, Zhang et al. discloses a kit, wherein the applicator element (72) is selected from the group consisting of a cotton bud (Column 5, line 62 – Column 6, lines 3), a foam bud, a felt tip, a flocked bud, and a tip made of ceramic or of sintered material.

In respect to claim 20 & 52, Zhang et al. discloses a kit, wherein the tube is free of an applicator element (Figure 1).

Regarding claim 22 & 54, Zhang et al. discloses a kit, wherein the plug comprises a liquid, and wherein said liquid is selected from the group consisting of mineral oils, fluorine-containing substances, and silicones (Column 5, lines 44 – 47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 & 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable

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over Zhang et al. in view of Lewis (US Patent No. 5,947,986).

With regard to claims 4 & 36, Zhang et al. discloses the kit with all of the aforementioned elements. However, Zhang et al. does not disclose a housing including compartments in which the applicators are housed. Lewis, however, discloses a housing (50 & 80) including compartments in which the applicators are housed. It would have been obvious to one having ordinary skill in the art at the time the invention in view of Lewis to incorporate a housing with Zhang et al. in order to hygienically store the applicators.

In regards to claims 5, 6, 37, & 38, Zhang et al. discloses a kit, wherein the housing includes at least one compartment configured to receive a single applicator or least one compartment configured to receive a plurality of applicators (Figure 1).

Additional Claim Rejections - 35 USC § 103

Claims 7, 8, 39, & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Zygmunt (US Patent No. 6,488,646).

In regards to claims 7 & 39, Zhang et al. discloses all of the aforementioned elements. However, Zhang et al. does not disclose at least one bag for packaging at least one applicator. Zygmunt discloses one bag (2) for packaging at least one applicator (Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Zygmunt to enclose a bag around an applicator with Zhang et al. in order to keep each applicator sterile.

In regards to claim 8 & 40, Zhang et al. in view of Zygmunt discloses the claimed

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invention except for a string of bags each containing at least one applicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a string of bags for each of the applicators, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Additional Claim Rejections - 35 USC § 103

Claims 9, 10, 41, & 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Barabino et al. (US Patent No. 4,740,194).

In regards to claim 9 & 41, Zhang et al. discloses an applicator that is labeled (Column 2, lines 57-58). However, Zhang et al. does not disclose each applicator includes at least one mark corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance. However, Barabino et al. discloses each applicator includes at least one mark corresponding to at least one of a type of test substance inside the tube and a concentration of a compound contained in the test substance (Column 6, lines 6-8). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Barabino et al. to include a marking on each applicator with Zhang et al. in order to differentiate applicators and their respective content.

In regards to claims 10 & 42, Zhang et al. in view of Barabino et al. discloses a kit, wherein the mark comprises at least one of an alphanumeric symbol and a color (Column 6, lines 6-8).

Additional Claim Rejections - 35 USC § 103

Claims 11, 12, 43, & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Tobin et al. (US Patent No. 3,792,699).

In regards to claims 11, 12, 43, & 44, Tobin et al. discloses a kit, wherein the test substance in the tube has a volume in a range from 0.01 ml to 5 ml or 0.05 ml to 1 ml. Tobin et al., however, discloses a kit, wherein the tube has a volume in the range of 0.01 ml to 5 ml or 0.05 ml to 1 ml (Column 3, lines 20-25). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Tobin et al. to have a volume in the range from 0.01 ml to 5 ml or 0.05 ml to 1 ml with Zhang et al. in order to sufficiently moisten the applicator region.

Additional Claim Rejections - 35 USC § 103

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barr et al. (US Patent No. 6,812,254).

In regards to claim 31, Zhang et al. discloses a kit with all of the aforementioned elements. However, Zhang et al. does not disclose a kit comprising at least two test substances with at least one compound at varying concentrations. Barr et al., however, discloses a kit capable of comprising at least two test substances with a substance capable of being at varying concentrations (Column 3, lines 44-65 & Column 7, line 40 – Column 8, line 38). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Barr et al. to have different test substances with varying concentrations with Zhang et al. in order to administer varying levels of treatment.

Additional Claim Rejections - 35 USC § 103

Claims 32 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Barr et al. (US Patent No. 6,812,254).

Regarding claim 32, Zhang et al. discloses a kit capable of comprising pharmaceutical products (Abstract). However, Zhang et al. does not teach of using a stimulating agent for stimulating a peripheral nervous system. However, Barr et al. teaches of using a stimulating agent for stimulating a peripheral nervous system (Abstract & Column 4, lines 5-23). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Barr et al. to use a stimulating agent for stimulating a peripheral nervous system with Zhang et al. in order to provide treatment for pains and discomforts (Column 1, lines 6 – 12).

In regards to claim 33, Zhang et al. in view of Barr et al. discloses a kit, wherein the stimulating agent for stimulating the peripheral nervous system is selected from the group consisting of natural or synthetic capsaicinoids, homocapsaicin, homodihydrocapsaicin, nordihydrocapsaicin, dihydrocapsaicin; lactic acid, glycolic acid, ethanol at a concentration greater than 50%, mustard seed oil (Barr et al., Column 3, lines 14-18).

In regards to claim 34, Zhang et al. in view of Barr et al. discloses a kit, wherein said stimulating agent comprises capsaicin (Barr et al., Abstract).

In regards to claim 35, Zhang et al. in view of Barr et al. discloses a kit, wherein a concentration of the stimulating agent for stimulating the peripheral nervous system lies in a range from 10-6% to 10-2% by weight (Barr et al., Column 3, lines 45-65).

Additional Claim Rejections - 35 USC § 103

Claims 71, 74, 76, 78, & 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Lewis (US Patent No. 5,947,986).

Regarding claim 71, Zhang et al. discloses a system capable of evaluating a sensitivity, wherein the tube (40) comprises: a first end (46) which is open, a second end which is closed in a first position (Figure 1, 42), a substance in said volume in said first position (Figure 1, 48), wherein said second end is movable to a second position which is open (Figure 2, 42), said substance being in communication with an outside of said container via said first open end (Figure 2, 46) in said second position (Figure 2), and wherein said second end is attached to said tube in, said second position (Figure 2, 42).

However, Zhang et al. does not disclose, a system comprising: packaging; and a plurality of tubes provided in said packaging. Lewis, however, discloses a system comprising of packaging and a plurality of tubes in the packaging (50 & 80). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Lewis to incorporate a housing with Zhang et al. in order to hygienically store the tubes.

In regards to claim 74, Zhang et al. in view of Lewis discloses a system, wherein each of said tube further comprises a removable plug (Zhang et al., 58) provided inside said tube in said first position, said removable plug defining a closed volume between said plug and said second end in said first position (Zhang et al., Figures 1 & 2).

In regards to claim 76, Zhang et al. in view of Lewis discloses a system, wherein said packaging comprises a box (Lewis, 50).

Regarding claim 78, Zhang et al. in view of Lewis discloses a system, wherein said packaging comprises: a stand (Lewis, 52); and a body (Lewis, 56) mounted on said stand.

With respect to claim 79, Zhang et al. in view of Lewis discloses a system, wherein each of said tubes (Lewis, 12) has a portion extending outside said body (Lewis, 56), and wherein said packaging further comprises a closure cap (Lewis, 60) coupled to said body and over said portions.

Additional Claim Rejections - 35 USC § 103

Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Lewis and further in view of Barr et al. (US Patent No. 6,812,254).

In regards to claim 73, Zhang et al. in view of Lewis discloses a system capable of comprising pharmaceutical products (Zhang et al, Abstract). However Zhang et al. in view of Lewis does not teach of a system, wherein said substance is a stimulating agent. Barr et al., however, teaches of a system, wherein said substance is a stimulating agent (Abstract & Column 4, lines 5-23). It would have been obvious to one

having ordinary skill in the art at the time the invention in view of Barr et al. to use a stimulating agent with Zhang et al. in view of Lewis in order to provide treatment for pains and discomforts (Column 1, lines 6 – 12).

Additional Claim Rejections - 35 USC § 103

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Lewis and further in view of Ohsumi (US Patent No. 5,658,981).

In regards to claim 75, Zhang et al. in view of Lewis discloses all of the aforementioned elements. However, Zhang et al. in view of Lewis does not disclose a system, wherein each of said tube further comprises a thermoreversible thickener inside the volume. Ohsumi, however, teaches the use of thermoreversible thickner (Abstract & Column 1, lines 43-52). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Ohsumi to add thermoreversible thickener to the volume with Zhang et al. in view of Lewis in order to control aqueous solutions, which thicken rapidly within a narrow temperature range (Column 1, lines 43-52).

Additional Claim Rejections - 35 USC § 103

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Lewis in view of Zygmunt (US Patent No. 6,488,646).

In regards to claim 77, Zhang et al. in view of Lewis discloses all of the aforementioned elements. However, Zhang et al. does not the packaging comprising of a plurality of bags, wherein each tube being in a bag. Zygmunt discloses one bag (2) for packaging at least one applicator (Figure 1). It would have been obvious to one having

ordinary skill in the art at the time the invention in view of Zygmunt to enclose a bag around an applicator with Zhang et al. in view of Lewis in order to keep each applicator sterile.

Futhermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a plurality of bags for each of the tubes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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